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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,149	10/24/2005	Nir Betser	003394.P020	2090

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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09/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



Office Action Summary

Application No.

10/529,149

Applicant(s)

BETSER ET AL.

Examiner

Christopher A. Flory

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90-131 is/are pending in the application.
- 4a) Of the above claim(s) 115-131 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 23 August 2007 have been fully considered but they are not persuasive. Claims 90-95 and 97-114 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tyler'462. Claims 90-95 and 97-114 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Maschino'956. Claim 96 stands rejected as variously stated by both Tyler'462 and Maschino'956.
2. Regarding the Applicant's argument concerning the limitation of claim 94 stating that the cuff comprises a first flexible resilient material having a different hardness from that of a second resilient material of the cuff, it is noted that the cited portions of Tyler'462 disclose selectivity of the spring constant or hardness of the cuff material, as well as that the sheet (cuff) may be made by laminating two or more materials together for added strength and that such materials are insulating. Specifically the act of laminating two materials together for additional strength would require that the two materials have different stiffness properties, since having the same stiffness would not increase the strength of the combined structure. Regarding Maschino'956, it is noted that column 7, lines 17-22 state that the cuff body might comprise a layer of silicone or PTFE and alternatively or additionally, sections of resilient fabric. Since silicone and a resilient fabric would have different hardnesses, the combination of the two reads on the claim.
3. Regarding Applicant's argument of the limitations in claim 97 that the cuff comprises a first flexible resilient material in the vicinity of the hole, and a second

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resilient material, it is first noted that the location of the second resilient material is not stated in the claim language, and therefore a second material in any portion of the prior art cuffs would read on the claim. Additionally, in both Tyler'462 and Maschino'956 the cuff is disclosed of being comprised of laminated or bonded materials of different hardnesses throughout as discussed in paragraph 2 above, and therefore the first material is present near the hole, as well as elsewhere, and the second material is also present near the hole, as well as elsewhere.

4. Regarding Applicant's argument directed to claim 106 wherein the flap forms an angle of between about 90 and about 180 degrees with a surface of the cuff, Figure 1 shows tab sections 70 (considered the entire planar section spanning the end of the substrate up to the first formed corrugation) on either end forming approximately a 90 degree angle to the first corrugation of what is considered the cuff portion. In Maschino'956, Fig. 1C clearly shows that the flaps of the closure form an angle of about 180 degrees, while Figures 5B and 6A show tabs 80 and 92 respectively forming an angle of 90 degrees to the cuff substrate. Additionally, the claim language calls for the flap to form a 90-180 degree angle with "a" surface of the cuff, not necessarily the immediately adjacent portion, and therefore since the cuffs of both art references are tubular in shape, the tab must necessarily be at an angle of 90-180 degrees with some surface of the cylindrical cuff.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 90-95 and 97-114 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tyler et al. (US 5,634,462, hereinafter Tyler'462).

Particular emphasis is placed on the abstract as well as Figures 7A-C and 8A-C.

Specifically regarding claims 94, 97 and 98, Tyler'462 discloses that the cuff may comprise more than one flexible resilient material and be of different hardness throughout (column 3, line 65 through column 4, line 3; column 6, lines 10-20 and 44-51; column 8, lines 1-5).

Specifically regarding claims 103 and 104, the device disclosed by Tyler'462 is capable of use by being placed around any one of the claimed tissues (abstract; column 3, lines 33-36).

7. Claims 90-95 and 97-114 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Maschino et al. (US 6,600,956, hereinafter Maschino'956).

Particular emphasis is placed on Figures 1A, 1C, 3, 5A-B and 6A and their related paragraphs.

Specifically regarding claims 90 and 94, Maschino'956 discloses that the cuff may comprise multiple insulating materials of different hardness (column 7, lines 17-22).

Specifically regarding claims 103 and 104, the device disclosed by Maschino'956 is capable of use by being placed around any one of the claimed tissues.

Claim Rejections - 35 USC § 102/103

8. Claim 96 stands rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tyler'462.

Regarding claim 96, it is understood that the Shore D hardness scale only contains values between 0 and 100, and therefore any measurable value on the durometer scale can be considered between about 4 and about 80. Tyler'462 would therefore inherently comprise a cuff having a hardness in this range. Alternatively, it would have been obvious to one having ordinary skill in the art at the time of the invention to chose a resilient material having a Shore D hardness between about 4 and about 80, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

9. Claim 96 stands rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Maschino'956.

Regarding claim 96, it is understood that the Shore D hardness scale only contains values between 0 and 100, and therefore any measurable value on the durometer scale can be considered between about 4 and about 80. Maschino'956 would therefore inherently comprise a cuff having a hardness in this range.

Alternatively, it would have been obvious to one having ordinary skill in the art at the time of the invention to chose a resilient material having a Shore D hardness between about 4 and about 80, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (*In re Aller*, 105 USPQ 233) or optimum value of a result effective variable (*In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

7 September 2007

/George Manuel/
Primary Examiner